Remarks

After careful consideration of the outstanding Office Action, this application is resubmitted for favorable reconsideration on the merits.

Before considering the rejection under 35 U.S.C. § 103(a), the undersigned acknowledges with appreciation the indicated allowability of claims 35 through 38 and 42 through 50. However, inasmuch as the Examiner has failed to establish a *prima facie* case of obviousness, those claims rejected ought also be allowed for reasons to be discussed immediately hereinafter.

Also, as a matter of housekeeping, at page 4, paragraph 5, the Examiner stated "Applicant's argument with respect to claims 20-50 have been considered but are moot in view of the new ground(s) of rejection." Since in the previous paragraph, the Examiner indicated that Claims 35 through 38 and 42 through 50 "would be allowable" and since only claims 30 through 34 and 39 through 41 were rejected in the previous paragraph, the undersigned interprets page 4, paragraph 5 to read:

> Applicant's arguments with respect to claims 30-34 and 39-41 have been considered but are moot in view of the new ground(s) of rejection.

If the undersigned has misinterpreted the Examiner's intention concerning the sentence appearing at page 4, paragraph 5, clarification would be appreciated.

The Examiner rejected claims 30 through 34 and 39 through 41 over the publications to Jacobs and Jaklitsch et al. identified in paragraph 3, bridging pages 2 and 3 of the outstanding Office Action.

At the top of page 3, first full paragraph, the Examiner begins the paragraph with the expression "Jacobs teaches." Thereafter, the Examiner lists as Jacobs teachings:

> a patient model; means for delivering the active substance at a present deliver rate; means for continuously communicating the present deliver rate to the patient model to calculate a present active substance concentration; control means for generating a control signal dependent upon the present active substance concentration and a desired active substance concentration; and means for controlling the delivery means to attain a delivery rate toward achieving the desired active substance (see page 107, section 'Model-Driven Drug Delivery'); wherein the former values of the active substance supplied to the patient's body include prior active substances; wherein the target value is adjusted/maintained; means for computing the target value dependent upon the patient.

With due decorum and courtesy, the latter-quoted description of the alleged Jacobs teaching is less than forthright. Insofar as the undersigned is concerned, all the Examiner has done is reproduced many of the limitations of claim 1, absent reference numerals or reference back to the Jacobs' publication in a reasonable and understandable fashion, and has attributed the limitations selected from the claims to structure which is nonexistent in the Jacobs publication. The Examiner is under a duty to provide a *prima facie* case of obviousness, as is set forth in the Manual of Patent Examining Procedure, Section 2142, which reads in part as follows:

> The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness....
>
> Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the 'differences,' conduct a search and evaluate the 'subject matter as a whole' of the invention. The tendency to resort to 'hindsight' based on applicant's disclosure is often difficult to avoid due to the very nature of the

> examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts **gleaned from the prior art.**
>
> The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. 'To support the conclusion that the claimed invention is directed to obvious subject matter, **either the references must expressly or impliedly suggest the claimed the invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.** (Emphasis added) (Ex Parte Clapp, 227 USPQ 972, 973, Bd. Pat. App. & Inter. 1985)

Section 2143.03 of the MPEP states:

> Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.

At Section 2143.03 of the MPEP is found the following requirement:

> To establish *prima facie* obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA) 1974.

It is quite clear from reading the first full paragraph at the top of page 3 of the outstanding Office Action that there is no parallel between that which is **required** by the MPEP and that which the Examiner has provided Applicant and his counsel.

The Supreme Court of the United States in Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) stated:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior

art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

It is incumbent upon the Examiner to define in an understandable and detailed manner the "scope and content" of the prior art, because absent the latter, one cannot proceed forward to analyze the remaining Graham factors/ conditions and move toward a legally proper decision with respect to the issue of obviousness/unobviousness. With due respect, the first full paragraph on page 3 of the outstanding Office Action is merely a restatement of Applicant's claim language, but there is no reference back, so to speak, which parallels Applicant's claim language to the alleged "scope and content" of the prior art Jacobs' publication. In other words, if Jacobs teaches "a patient model," the Examiner must not merely allege Jacobs teaches such but must advise Applicant where such teaching exists in the publication unless, of course, it is readily apparent. Obviously, the Examiner is not required to state the obvious, but he ought not attribute structure to the Jacobs publication which is **nonexistent**.

As one example, under the heading "Model-Driven Drug Delivery," Jacobs states that a physician first specifies "a desired (setpoint) plasma drug concentration (Cp_d)" based upon "monitored and anticipated patient response, on the current estimate of the plasma drug concentration, and on the pharmacological properties of the drug being administered." Thereafter at frequent intervals (ΔT) the setpoint is compared with the "current prediction of the plasma drug concentration (Cp_p), which is computed by

real-time simulation of a phramacokinetic model of the drug being infused." "Any difference between Cp_d and Cp_p is acted on by a pump-controlled algorithm to generate an infusion rate to achieve or re...tain [sic - illegible in our copy] the setpoint." The latter "difference" generates the "infusion rate" and the so generated "infusion rate is transmitted electronically to the drug infusion pump, which delivers drug to the patient." Therefore, this publication deals basically with nothing other than achieving a difference between Cp_d and Cp_p which through the algorithm controls drug delivery by the infusion pump. This seems quite familiar to that which has occurred in the past, namely, computer comparison of desired and simulated drug concentrations to arrive at infusion rates.

There is **nothing** in the Jacobs publication which corresponds to limitation c) of claim 30, for example, dealing with the calculation of "a **present** active substance concentration (CN_{actual}) in the patient's body." Additionally, limitation d) in claim 30 depends upon the latter calculation to control the control means (17) for generating the necessary control signal to attain the desired active substance concentration ($CN_{desired}$) per limitation (e). If the Examiner believes the latter two limitations are found somewhere in the Jacobs publication, he is respectfully requested to designate exactly where "Jacobs teaches the latter two limitations." With due respect, no such teachings exists, and absent the same, the obviousness rejection must fall. Accordingly, the withdrawal of the 35 U.S.C. § 103(a) rejection based upon the Jacobs and Jaklitsch et al. publications is considered proper and would be most appreciated.

The undersigned appreciates that the Examiner has stated in the last full paragraph on page 3 of the Office Action:

> Jacklitsch [sic] teaches an anesthetic controller using a patient model created from former values of an active substance previously delivered to other patients (Page 583, Chapter II).

Whether true or false is immaterial since the latter is conventional and has no bearing on the unobvious subject matter of claim 30. The undersigned has absolutely no problem with the Examiner utilizing the Jaklitsch et al. publication, but the prior art "as a whole" [Graham, supra] fails to render obvious the subject matter of claim 30.

In view of the foregoing, the formal allowance of claim 30 and each of the claims depending therefrom is considered proper and would be most appreciated.

Accordingly, the formal allowance of this application at an early date is herewith respectfully requested.

Respectfully submitted,

DILLER, RAMIK & WIGHT

By: _____
Vincent L. Ramik, Reg. No. 20,663

7345 McWhorter Place
Suite 101
Annandale, VA 22003

e-mail: DRWPATENTLAW@AOL.COM